

5 of side elements each defining a path extending at least partially
6 longitudinally along the wall and at least partially circumferentially around
7 the wall,

8 a plurality of leaflets, each leaflet thereof having a body extending
9 from a wall-engaging outer edge to an inner edge proximate a
10 corresponding inner edge of at least one other leaflet of the plurality of
11 leaflets,

12 the inner edges of said plurality of leaflets cooperable to define an
13 opening therebetween to permit fluid flow in a first direction along the
14 bodily passage, and further cooperable to engage each other sufficiently to
15 restrict fluid flow in a second direction opposing the first direction,

16 the outer edge of each one of the plurality of leaflets attached along
17 one side element of said plurality of side elements and thereby adapted to
18 engage the wall of the bodily passage in said path extending at least
19 partially longitudinally and at least partially circumferentially such that the
20 leaflet extends along said bodily passage away from the inner edges in said
21 second direction.

B2 1 5. (Amended) The implantable valve of claim 3 wherein said frame
comprises wire to and around which the bodies of the leaflets are secured.

B3 1 6. (Amended) The implantable valve of claim 1 wherein the plurality of
2 leaflets includes two leaflets such that when the frame is substantially
3 flattened, it assumes a diamond shape with the inner edges of the two
4 leaflets defining a slit therebetween.

B3 1 10. (Amended) The implantable valve of claim 1 wherein the plurality of
2 leaflets comprise an extracellular collagen matrix.

B4 1 19. (Amended) An implantable valve for a bodily passage of tubular
2 shape, comprising:

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3 a frame that includes a plurality of legs, each of the legs originating
4 from a pair of bends located about a first end of the implantable valve, and
5 extending in an opposite direction therefrom, each of the plurality of legs
6 terminating at the second end of the implantable valve such that the
7 plurality of legs generally assume a serpentine configuration along the
8 circumference of a bodily passage when situated therein,

9 a plurality of leaflets, each leaflet comprising a covering that includes
10 one or more flexible materials, the leaflet including a body that comprises
11 a wall-engaging outer edge and an inner edge, the outer edge at least
12 partially attached to, and reinforced by one of the plurality of legs, the outer
13 edge and the associated leg adapted to sealingly engage the inner wall of
14 the bodily passage,

15 wherein the body of the leaflet extends inward from the wall of the
16 bodily passage and extending toward the first end of the implantable valve
17 where it terminates at the inner edge, the body and inner edge traversing
18 the lumen of the bodily passage when situated therein and being
19 configured such that the leaflet is cooperable with at least one other leaflet
20 to define an opening that permits positive flow of fluid therethrough in a
21 first direction, while the plurality of leaflets are further adapted to trap
22 between the leaflets and the inner wall of the bodily passage fluid flowing
23 in a second direction opposite the first direction and seal against one
24 another to restrict fluid flow in said second direction.

1 36. (Amended) An implantable vascular valve comprising:

2 a covering including first and second oppositely facing curvilinear
3 surfaces when positioned across a vascular opening and also including at
4 least a first arcuate outer edge that exerts pressure against, and at least
5 forms a partial seal with, a vascular wall when positioned thereagainst; the
6 covering adapted to trap fluid in a curved structure defined by the arcuate
7 edge;

8 wherein the covering also includes an orifice extending through the
9 oppositely facing curvilinear surfaces;
10 wherein the covering traps fluid in said curved structure and the
11 orifice is in a closed position blocking fluid flow therethrough when fluid is
12 applied to the first oppositely curvilinear surface with the valve positioned
13 across the vascular opening; and
14 wherein the orifice is in an open position permitting fluid flow
15 therethrough when fluid is applied to the second oppositely curvilinear
16 surface with the valve positioned across the vascular opening.

1 46. (Amended) An implantable valve for a bodily passage of tubular
2 shape, comprising:

3 a frame having a pair of legs, the frame being radially expandable
4 against the walls of the bodily passage wherein the legs define a path
5 extending at least partially longitudinally along the walls and at least
6 partially circumferentially around the walls,

7 a plurality of leaflets comprising material derived from small
8 intestinal submucosa, each leaflet thereof having a body extending from a
9 wall-engaging outer edge to a free edge proximate a corresponding free
10 edge of at least one leaflet of the plurality of leaflets, the wall-engaging
11 outer edge of the leaflet being at least partially reinforced by one of the
12 plurality of legs of the frame,

13 the free edges of said plurality of leaflets cooperable to define an
14 opening therebetween to permit fluid flow in a first direction along said
15 bodily passage, and further cooperable to engage each other sufficiently to
16 restrict fluid flow in a second direction opposing the first direction,

17 the outer edge of each said leaflet attached along one leg of the pair
18 of legs and thereby adapted to engage the walls of the bodily passage
19 oriented at least partially longitudinally the walls and at least partially

20 circumferentially around the walls and such that the leaflet extends along
21 said bodily passage away from the free edges in said second direction,
22 at least a portion of the body of each said leaflet being flexible at
23 least proximate the free edge thereof, and
24 the plurality of leaflets having a first shape when unconstrained and
25 relaxed and being compressible into a second shape of smaller general size
26 for delivery to a treatment site in said bodily passage, and being
27 expandable at said treatment site upon delivery thereto for the outer edges
28 of said leaflets to sealingly engage the passage wall while the free edges
29 of the bodies of all said leaflets are moveable into and out of engagement
30 with each other in response to fluid flow.

1 47. (Amended) An implantable valve for a bodily passage of tubular shape,
2 comprising:

3 a self-expanding frame that includes a pair of legs, each of the legs
4 originating from a pair of bends located about a first end of the implantable
5 valve, and extending in an opposite direction therefrom, each of the pair of
6 legs terminating about the second end of the implantable valve such that
7 the pair of legs generally and collectively assume a serpentine
8 configuration along the circumference of a bodily passage when situated
9 therein;

10 a plurality of barbs, at least one barb attached to each of the pair of
11 legs, at least one of the barb including a terminal projection, the terminal
12 projection configured to releasably engage with a delivery system for
13 deployment of the implantable valve into the bodily passage;

14 a pair of leaflets, each leaflet comprising tissue derived from an
15 extracellular collagen matrix, each of the leaflets including a body that
16 comprises a wall-engaging outer edge and an inner edge, the outer edge
17 at least partially attached to, and reinforced by the frame, the outer edge
18 and the associated leg adapted to sealingly engage the inner wall of the
19 bodily passage,

20 wherein the body of the leaflet extends inward from the wall of the
21 bodily passage and extending toward the first end of the implantable valve
22 where it terminates at the inner edge, the body and inner edge traversing
23 the lumen of the bodily passage when situated therein and being
24 configured such that the leaflet is cooperable with the other of the plurality
25 of leaflets to define an opening that permits positive flow of fluid
26 therethrough, while the pair of leaflets are further adapted to trap fluid
27 between the leaflets and the inner wall of the vessel and seal against one
28 another to restrict retrograde flow.

29

1 ~~48~~ (New claim number) 48. The implantable valve of claim 19 wherein
2 the frame is formed into the serpentine configuration.

1 ~~49~~ (New claim number) 49. The implantable valve of Claim 19 wherein
2 the frame comprises a bioabsorbable material.

B7 Please add the following new claims:

1 50. (New) An artificial valve prosthesis for placement within a bodily
2 passage of a patient, the valve comprising:
3 a plurality of leaflets comprising an inner edge and an outer edge;
4 a supporting frame extending along the outer edge of each of the
5 plurality of leaflets such that the outer edges thereof resiliently conform
6 with the contours of the bodily passage when placed therein and exert a
7 radial force thereagainst;
8 wherein the supporting frames extending along each leaflet of the
9 plurality of leaflets are interconnected by a series of bends such that they
10 collectively assume a generally serpentine configuration; and
11 wherein the inner edges of the plurality of leaflets traverse the vessel
12 lumen such that the plurality of leaflets are cooperable to define an opening
13 therebetween to permit fluid flow in a first direction along the bodily

14 passage, while engaging each other sufficiently to restrict fluid flow in a
15 second direction opposing the first direction.

1 51. (New) An artificial valve prosthesis for placement within a bodily
2 passage of a patient, the valve comprising:

3 a plurality of legs each comprising a leaflet having an inner edge and
4 an outer edge, and a support frame attached along the outer edge of the
5 leaflet;

6 wherein the plurality of legs are interconnected such that the support
7 frame includes a serpentine configuration in which the outer edges of the
8 leaflets exert radial force against the walls of bodily passage and generally
9 conform to the contours thereof; and

10 wherein the inner edges of the plurality of leaflets traverse the vessel
11 lumen such that the plurality of leaflets are cooperable to define an opening
12 therebetween to permit fluid flow in a first direction along the bodily
13 passage, while engaging each other sufficiently to restrict fluid flow in a
14 second direction opposing the first direction.

1 52. (New) The implantable valve of claim 51, wherein the plurality of legs
2 each include a first and second bend oriented in a first direction and at least
3 one bend oriented in an opposite direction such that the leaflet and
4 supporting frame thereof generally comprise a 'V' or 'U' shape.

1 53. (New) The implantable valve of claim 51, wherein the plurality of legs
2 comprise three legs oriented approximately 120° apart with respect to one
3 another.

1 54. (New) The implantable valve of claim 51, wherein the plurality of legs
2 comprise four legs oriented approximately 90° apart with respect to one
3 another.

1 55. (New) An implantable valve for a bodily passage of tubular shape,
2 comprising:
3 a support frame configured for expansion to conform to a wall of the
4 bodily passage, said support frame when expanded providing a plurality
5 of side elements each defining a path extending at least partially
6 longitudinally along the wall and at least partially circumferentially around
7 the wall,
8 a plurality of leaflets comprising a extracellular collagen matrix
9 material, each leaflet thereof having a body extending from a wall-
10 engaging outer edge to an inner edge proximate a corresponding inner
11 edge of at least one other leaflet of the plurality of leaflets,
12 the inner edges of said plurality of leaflets cooperable to define an
13 opening therebetween to permit fluid flow in a first direction along the
14 bodily passage, and further cooperable to engage each other sufficiently to
15 restrict fluid flow in a second direction opposing the first direction,
16 the outer edge of each one of the plurality of leaflets attached along
17 one side element of said plurality of side elements and thereby adapted to
18 directly engage the wall of the bodily passage therearound and provide
19 ingrowth of adjacent native tissue into the extracellular collagen matrix
20 material.

Remarks

In the Office action of September 11, 2002, Paper No. 22, claims 1-47 are pending with claims 7-9,14,17,18,23,24,31-35 and 42-45 having been withdrawn from consideration. Claims 1-6,10-13,15,16,19-22,25-30,36-41, and 46-47 are rejected. Two misnumbered claims are objected to. In particular, claims 1-6,10-13,15,16, and 36-41 were rejected because the Examiner feels that the best mode contemplated by the inventor has not been disclosed. Claims 4,19-22, and 25-30 were rejected under 35 U.S.C. 112 first paragraph as containing subject matter that the Examiner feels